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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/865,905	05/24/2001	Jeffrey H. Burbank	264/163	6268

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EXAMINER

BIANCO, PATRICIA

ART UNIT PAPER NUMBER

3762

DATE MAILED: 02/11/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/865,905

Applicant(s)

BURBANK ET AL.

Examiner

Patricia M Bianco

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-10, 13-25 and 33-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10, 13-25 and 33-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 5 & 8.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election of Group I, Species B (claims 1-25 & 28-32) in Paper No. 11 is acknowledged. Because applicant did not distinctly and specifically state if the election was with or without traverse and did not specifically point out any supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant filed an amendment with the election canceling claims 11, 12 & 26-32, adding new claims 33-35 and amending claims 1, 10 & 21. As a result, the current claims pending are 1-10, 13-25 & 33-35, all of which have been examined on the merits.

### ***Oath/Declaration***

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:  
The specification to which the oath or declaration is directed has not been adequately identified. See MPEP § 601.01(a).

### ***Specification***

Applicant has indicated co-pending applications in the first paragraph of the specification. The first page of the specification should be updated to clarify the status of all related applications noted in the first paragraph of the specification. The status of

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nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. \_\_\_\_\_" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

### ***Drawings***

The drawings were received on 01/16/02. These drawings are accepted.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim **21** is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The limitation added beginning with "the second panel comprising a second compartment to receive a volume of the second fluid, the second compartment communicating with third and fourth channels" spanning lines 6-12 of the claim is confusing and redundant. Applicant first recites a second panel comprising a second compartment communicating with third and fourth channels in lines 4-6. It is unclear if the amendment is a typographical error or if the second panel is to further include an additional compartment (i.e. third compartment). Correction is required.

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Claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The limitation the recitation of "*first and second fluid separate compartments flexible fluid chambers with respective inner compartments*" spanning lines 2-3 of the claim is confusing. Does this mean that the first and second fluid separate compartments are flexible? Or are the fluid separate compartments a separate and distinct structural feature from the flexible fluid chambers? Correction is required.

Claim 1 recites the limitation "the second surface" in line 9 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 1 recites the limitation "the first surface" in line 11 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 1 recites the limitation "the first channel" in lines 11-12 of the claim. There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims **1-10, 13-20 & 33-35** are rejected under 35 U.S.C. 102(e) as being anticipated by Beden et al. (5,871,694). Beden et al. (hereafter Beden) discloses a fluid balancing unit (14) for use in blood purification devices. The balancing unit comprising first (12) and second (17) chambers separated by an intermediate sheet (13) for holding and discharging fluids. The unit is made of flexible plastic sheets (40,41) that are heat-sealed along seams to form multiple chambers for holding and discharging fluid. Beden also teaches that the unit is disposable. As fluid fills one of the chambers, fluid is discharged from the other chamber maintaining an even and balanced flow. Tubing is embedded within the unit and clamping regions are included. The structure of the chamber allows for a smooth displacement of fluid from the chamber. The unit is placed in receiving bodies (45,46) which forms a fixed volume vessel. The vessel has movable pressure plates (seen to be equivalent to the actuator of applicant's claims) that act upon the fluid chambers to maintain equalization. The replacement and waste fluids are seen to be a first and a second fluid. (See figures. 2-5 and col. 3, line 53-col. 6, line 20).

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### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims **1-10 & 13-20** are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 119, 120 & 122-134 of copending Application No. 10/041,949 (2002/0147423) in view of US Patent 6,554,789. The claims of application 10/041,949 substantially disclose a flow management system as claimed in claims 1-10 & 13-25 of the instant application except for having at least one support element to hold the first and second compartments. However, in US Patent 6,554,789, discloses an analogous fluid/flow management circuit including a tray that defines an interior space and holds the fluid circuit within said space. At the time of the invention, it would have been obvious to one having skill in the art to modify the claimed invention of 10/041,949 to be held within a tray to ensure that the panels remain in an overlay position.

This is a provisional obviousness-type double patenting rejection.

Claims **21-25** are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 119, 120, & 122-134 of copending Application No. 10/041,949 (2002/0147423). Although the conflicting claims are not identical, they are not patentably distinct from each other because the only difference is the limitation added beginning with "the second panel comprising a second compartment to receive a volume of the second fluid, the second compartment communicating with third and fourth channels" spanning lines 6-12 of claim 21, which is redundant (see 35 USC 112, 2<sup>nd</sup> paragraph rejection above). Applicant first recites a second panel comprising a second compartment communicating with third and fourth channels in lines 4-6. Aside from this limitation the claims are identical.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims **33-35** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 44/39 of U.S. Patent No. 6,579,253. Although the conflicting claims are not identical, they are not patentably distinct from each other because the application claims are a broader recitation of the patent claims since it does not require a fluid processing device. However, the processing includes actuators and in-line clamping regions in the first and second flow paths to simultaneously occlude the lines of the fluid circuit.




***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia M Bianco whose telephone number is (703) 305-1482. The examiner can normally be reached on Monday to Friday 9:00-6:30, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

February 8<sup>th</sup>, 2004

  
Patricia M Bianco  
Primary Examiner  
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